

## **REMARKS**

### **Amendments to the Specification**

The Amendment to the Specification simply corrects an obvious typographical error. No new matter has been added.

### **Amendments to the Claims**

Claims 1-12 are pending. Claims 7, 8 and 12 are cancelled. Claims 1, 2 and 10 are amended. Support for the claim amendments can be found throughout the specification and at least in former claims 7 and 8. Claim 2 is amended solely to correct the grammar. After entry of this amendment claims 1-6, 9-11 and 13-19 remain pending, with claims 13-19 withdrawn. No new matter has been added.

### **Response to Claim Rejection under 35 USC Section 112:**

Applicant has taken note of the rejection of claim 10 as being indefinite for reciting "molecular weight of about between 7 kDa and several hundreds kDa". As the term "and several hundreds kDa" has been removed, the rejection for indefiniteness is now rendered moot. The claim now precisely defines a minimum limit for the molecular weight of the chitosan polymer which is of at least about 7 kDa, as supported by the description presently on file. The Examiner is respectfully requested to withdraw the rejection.

### **Response to Claim Rejection under 35 USC Section 102(b) - BERTHOLD:**

Applicant has taken note of the rejection of claims 1-6 and 9-12 as being anticipated by BERTHOLD et al. As the present claims have been restricted to methods that use a combination of at least two salts wherein the combination is of kosmotropic and chaotropic salts, and it has been specified that the claimed method "consists of" the claimed step (i.e., no unclaimed elements such as emulsifiers are added), this rejection is therefore rendered moot.

### **Response to Claim Rejection under 35 USC Section 102(b) - STRUSZCZYK:**

Applicant has taken note of the rejection of claims 1-4, 6 and 9-12 as being anticipated by STRUSZCZYK et al. (WO 03/066682). This reference uses an alkali to

precipitate chitosan. The pH of the mixture therefore becomes basic (i.e., alkaline). As indicated above, the present claims have been restricted to methods that use a combination of at least two salts wherein the combination is of kosmotropic and chaotropic salts, and it has been specified that the claimed method “consists of” the claimed step (i.e., no unclaimed elements are added), this rejection is therefore rendered moot.

**Response to Claim Rejection under 35 USC Section 102(b) - ANDERSON:**

Applicant has taken note of the rejection of claims 1-7 and 9-11 as being anticipated by ANDERSON et al. (GB 2385050). Again, the present claims have been restricted to methods that use a combination of at least two salts wherein the combination is of kosmotropic and chaotropic salts, and it has been specified that the claimed method “consists of” the claimed step (i.e., no unclaimed elements are added), this rejection is therefore rendered moot. rejection

**Response to Claim Rejection under 35 USC Section 102(b) - SANNAN:**

Applicant has taken note of the rejection of claims 1-4, 6-9 and 11 as being anticipated by SANNAN et al. (US 4267313). Applicant respectfully disagrees with the Examiner's interpretation of this publication. Indeed, Applicant respectfully submits that SANNAN et al. did not use a composition of sodium isocyanate as a chaotropic agent and an alkaline base to precipitate chitosan. The description indicates that sodium isocyanate was used as a reagent to convert the primary amino group of the glucosamine moiety of chitosan into a ureido derivative. The chemical reaction formula, as illustrated, shows chitosan being converted into carbamoyl-chitosan as a result of the treatment of chitosan with sodium isocyanate. Applicant therefore respectfully submits that SANNAN et al. shows an alkali-based method to precipitate carbamoylated chitosan from a reaction mixture containing carbamoylated chitosan and sodium isocyanate and not chitosan. It would be obvious to a person versed in the art that the chemical and physical properties of carbamoylated chitosan would be different from chitosan. The Examiner is therefore respectfully requested to withdraw the rejection.

**Response to Claim Rejection under 35 USC Section 103(a) – MALLON, SINGLA & BERTHOLD:**

Applicant has taken note of the Examiner's rejection of claims 1 to 12 as being unpatentable over MALLON et al. in view of SINGLA et al. and BERTHOLD et al. Applicant respectfully disagrees with the Examiner's interpretation of the cited documents. Without making any admission regarding the applicability of MALLON et al., Applicant respectfully submits that BERTHOLD et al. teaches away from the claimed method. The method of BERTHOLD et al. to precipitate chitosan in microspheres necessitates additional elements such as polysorbate, an emulsifier. No such additional elements are necessary to practice the presently claimed method. Indeed, claim 1 has been amended to exclude the addition of any unclaimed elements in the precipitation process, by reciting that the claimed method is a method "consisting of" the claimed step. Given this, Applicant does not see how or why a person versed in the art wishing to practice the methods of BERTHOLD et al. in light of the teachings of MALLON et al. would precipitate chitosan in the presently claimed manner. To the contrary, if the teachings of BERTHOLD et al. were to be applied, then a person versed in the art would be led to believe that the presence of other elements such as emulsifiers are necessary in order to precipitate chitosan and therefore would not be practicing the presently claimed method. For all of these reasons, Applicant respectfully submits that the presently claimed method is inventive over the cited prior art documents and respectfully requests that the Examiner withdraw this rejection.

**Response to Claim Rejection under 35 USC Section 103(a) – SANNAN & BERTHOLD:**

Applicant has taken note of the Examiner's rejection of claims 10 and 12 as being unpatentable over SANNAN et al. in view of BERTHOLD et al. Claim 12 has been cancelled, rendering its rejection moot. Claim 10 depends from claim 1 and further specifies that the chitosan polymer has a molecular weight of at least about 7 kDa. As discussed above, Applicant respectfully submits that BERTHOLD et al. teaches away from the claimed method. The method of BERTHOLD et al. to precipitate chitosan in microspheres necessitates additional elements such as polysorbate, an emulsifier. No such additional elements are necessary to practice the presently claimed method. Indeed, claim 1 has been amended to exclude the addition of any unclaimed elements in the precipitation process, by

reciting that the claimed method is a method “consisting of” the claimed step. Given this, Applicant does not see how or why a person versed in the art wishing to practice the methods of BERTHOLD et al. in light of the teachings of SANNAN et al. would precipitate chitosan in the presently claimed manner. To the contrary, if the teachings of BERTHOLD et al. were to be applied, then a person versed in the art would be led to believe that the presence of other elements such as emulsifiers are necessary in order to precipitate chitosan and therefore would not be practicing the presently claimed method. For all of these reasons, Applicant respectfully submits that the presently claimed method is inventive over the cited prior art documents and respectfully requests that the Examiner withdraw this rejection.

### **Conclusion**

Applicant would like to thank the Examiner for his/her time and consideration of this case. If a telephone conversation would help clarify any issues, or help expedite prosecution of, this case, Applicant invites the Examiner to contact the undersigned at (617) 248-5222. Additionally, please charge any fees that may be required or credit any overpayment to our Deposit Account 03-1721.

Respectfully Submitted,  
CHOATE, HALL & STEWART LLP

Date: December 9, 2010

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